PART II
REGISTRATION OF X-RAY MACHINES AND SERVICES

RHB 2.1 Scope. This part provides for the registration of x-ray machines, (controls and tubes), and facilities, and for the registration of persons providing x-ray machine installation, servicing, and/or services.

2.1.1 Except as specifically exempted in RHB 2.2, each person who receives, possesses, uses, or acquires an x-ray machine shall register the control and tubes of such machine with the Department in accordance with the requirements of this Part.

2.1.2 In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of these regulations.

RHB 2.2 Exemptions.

2.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2.2.2 Television receivers, video display terminals, and computer monitors, when used without modification to their internal or external construction, are exempt from the requirements of this Part.

2.2.3 Any facility where a federal agency has exclusive jurisdiction is exempt from the requirements of this Part.

2.2.4 X-ray machines while in transit or storage incident thereto are exempt from the requirements of this Part.

RHB 2.3 Application and Review Fees.

2.3.1 Application Fee. Each registrant shall pay a non-refundable application fee of sixty two dollars and fifty cents upon submission of the initial Facility Registration Approval Request form. A facility registration approval shall not be issued until payment of the application fee.

2.3.2 Shielding Plan Review Fee. Each registrant shall pay a non-refundable shielding plan review fee of sixty two dollars and fifty cents per x-ray control upon submission of any shielding plan. A shielding plan approval shall not be issued until payment of the review fee.

RHB 2.4 Facility Registration Approval.

2.4.1 Fixed Installation-Fixed Facility. Any facility planning to install an x-ray producing machine in a fixed location shall meet the provisions of this Subpart.

2.4.1.1 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit to the Department the following information:

2.4.1.1.1 Facility Name, Location Address, and Mailing Address;

2.4.1.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.1.1.3 Type and make of x-ray equipment to be installed;

2.4.1.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1, 7.8.3, or 8.8;

2.4.1.1.5 A training plan as required by RHB 4.2.3,7.8.1, or 8.11;

2.4.1.1.6 A shielding plan, if required by RHB 4.4 or 8.13.2;

2.4.1.1.7 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information shall be provided for all companies involved.

2.4.1.2 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3.

2.4.1.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.1.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.2 Fixed Installation-Mobile Facility. Any facility planning to install an x-ray producing machine in a fixed location of a mobile facility shall meet the provisions of this Subpart.

2.4.2.1 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit to the Department the following information:

2.4.2.1.1 Facility Name and Mailing Address where correspondence may be sent;

2.4.2.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.2.1.3 Type and make of x-ray equipment to be installed;

2.4.2.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1, 7.8.3, or 7.8;

2.4.2.1.5 A training plan as required by RHB 4.2.3, 7.8.1, or 8.11;

2.4.2.1.6 An operating schedule, indicating when and where the equipment will be used;

2.4.2.1.7 A shielding plan, as required by RHB 4.4 or 8.13.2;

2.4.2.1.8 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale or installation, then the above information shall be provided for all companies involved.

2.4.2.2 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit any application and shielding review fees as required by RHB 2.3.

2.4.2.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.2.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.3 Mobile or Portable Equipment. Any facility acquiring or using mobile or portable x-ray producing equipment shall meet the provisions of this Subpart.

2.4.3.1 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit to the Department the following information:

2.4.3.1.1 Facility Name, Location Address and Mailing Address;

2.4.3.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.3.1.3 Type and make of x-ray equipment to be used;

2.4.3.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1, 7.8.3, or 7.8;

2.4.3.1.5 A training plan as required by RHB 4.2.3,7.8.1, or 8.11.

2.4.3.1.6 The name, address, and contact person of the company selling the equipment. If more than one company is involved in the sale, then the above information shall be provided for all companies involved.

2.4.3.2 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit any application and shielding review fees as required by RHB 2.3.

2.4.3.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.3.4 A facility shall not use any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.4 It shall be unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has received a facility registration approval from the Department.

RHB 2.5 Equipment Registration Requirements, Users of X-ray Machines.

2.5.1 Initial Equipment Registration. Every person who possesses an x-ray machine shall register the machine's control and tubes with the Department, within thirty days of the date of acquisition. Registration shall be made on Form DHEC 819, "Registration of X-Ray Producing Machines", furnished by the Department.

2.5.1.1 Upon registration of a control, the Department shall issue the facility a registration sticker to be placed on each control. The registration sticker shall be placed on the control panel in a clearly visible location.

2.5.1.2 When a control is removed from a facility, the facility shall remove the registration sticker.

2.5.1.3 A registration sticker on a control, displaying the facility's proper name, shall be considered indicative of a facility's and a control's registration status, as required to be confimed by RHB 2.7.2.

2.5.2 Renewal of Equipment Registration. The Department shall provide an annual re-registration statement to all registrants. The re-registration statements shall be reviewed, corrected, signed, and returned to the Department within 30 days.

2.5.3 Report of Change. The registrant shall report to the Department, within thirty days, any changes of status affecting any x-ray machine or facility. Report of a change of status shall be made in writing, and forwarded to the Department.

2.5.4 Verification of Service Representative. Each registrant shall require any person furnishing x-ray machine servicing or services as described in this Part to provide evidence that he has been registered with the Department as a vendor in accordance with these regulations.

2.5.5 Leasing of Equipment. When a facility leases x-ray equipment, it shall be the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet these regulations.

RHB 2.6 Registration Requirements-Servicing and Services (VENDOR)

2.6.1 Each person who is engaged in the business of selling, leasing or installing or offering to sell, lease or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish any equipment services in this State shall apply for registration as a vendor with the Department within thirty days following the effective dates of these regulations or thereafter prior to furnishing or offering to furnish any such services.

2.6.2 Application for vendor registration shall be completed on forms DHEC 824 and DHEC 825, furnished by the Department and shall contain all information required by the Department as indicated on the forms, and accompanying instructions. This information shall include:

2.6.2.1 The name, address, and telephone number of the individual or company to be registered, along with the owner(s) of the company;

2.6.2.2 The description of the services to be provided;

2.6.2.3 The name, training, and experience of each person who provides services;

2.6.2.4 The date of the application and the signature of the individual responsible for the company;

2.6.2.5 A sample of equipment performance test procedures and forms;

2.6.2.6 A sample of a shielding plan, if registering as a Class III or Class IV vendor;

2.6.2.7 Any additional information the Department determines to be necessary for evaluation of the application for registration;

2.6.3 Each person applying for registration under this Part shall specify that he has read and understands the applicable requirements of these regulations.

2.6.4 For the purpose of this section, equipment services are:

2.6.4.1 Direct sale and transfer of radiation machines and machine components to end users.

2.6.4.2 Installation or servicing of radiation machines and associated radiation machine components;

2.6.4.3 Diagnostic radiographic facility and shielding design;

2.6.4.4 Diagnostic fluoroscopic facility and shielding design;

2.6.4.5 Diagnostic area radiation survey, e.g., shielding evaluation;

2.6.4.6 Radiation instrument calibration;

2.6.4.7 Therapeutic facility and shielding design, area radiation surveys, or calibration;

2.6.4.8 Personnel dosimetry services;

2.6.4.9 General health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys; and

2.6.4.10 Such other equipment services which can affect compliance with these Regulations by a registrant, as determined by the Department.

2.6.5 Report of Change. The vendor shall notify the Department in writing, within thirty days of any changes which would render the information contained in the Application for Registration no longer accurate. Report of changes shall be made for changes in employee's status.

2.6.6 Training and Educational Requirements for Equipment Services. Each person registered pursuant to RHB 2.6 shall be qualified by reason of education, training and experience to provide the service for which registration is requested. The following are minimum qualifications for specific types of services:

2.6.6.1 Class I - Sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules and regulations which govern the possession, installation and use of radiation machines in South Carolina.

2.6.6.2 Class II - Installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:

2.6.6.2.1 Manufacturer's equipment school for service, or equivalent training,

2.6.6.2.2 Maintenance and installation for the type of machine use (e.g., dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;

2.6.6.2.3 Training in principles of radiation protection; and three to six months of experience in installation and service of radiation machines and machine components.

2.6.6.3 Class III - Diagnostic radiographic facility and shielding design:

2.6.6.3.1 Formalized training in principles of radiation protection;

2.6.6.3.2 Formalized training in shielding design; and

2.6.6.3.3 One year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.

2.6.6.4 Class IV - Diagnostic fluoroscopic facility and shielding design:

2.6.6.4.1 Formalized training in principles of radiation protection;

2.6.6.4.2 Formalized training in shielding design; and

2.6.6.4.3 One year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

2.6.6.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation:

2.6.6.5.4 Formalized training in basic radiological health;

2.6.6.5.2 Formalized training in shielding evaluation; and one year of experience performing area radiation surveys.

2.6.6.6 Class VI - Radiation instrument calibration:

2.6.6.6.1 The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration;

2.6.6.6.2 Training in principles of radiation protection;

2.6.6.6.3 Training in operation and calibration of radiation detection and measurement instrumentation;

2.6.6.6.4 One year experience in an instrument calibration laboratory;

2.6.6.6.5 Shall submit a description of the procedures that will be utilized in performing instrument calibrations.

2.6.6.7 Class VII - Therapeutic facility and shielding design, area radiation survey, or calibration:

2.6.6.7.1 Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x-ray and gamma ray physics, or certification by the American Board of Medical Physics in therapeutic radiological physics; or

2.6.6.7.2 Having the following minimum training and experience:

2.6.6.7.2.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics;

2.6.6.7.2.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine;

2.6.6.7.3 Shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed.

2.6.6.7.4 Shall submit a copy of all forms, reports and documents that will be supplied to registrants; and shall submit one sample of each specific type, e.g., therapy, accelerator.

2.6.6.8 Class VIII - Personnel dosimetry service: The applicant must hold current personnel dosimetry service accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.

2.6.6.9 Class IX - General health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys:

2.6.6.9.1 Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics;

2.6.6.9.2 Graduate training in medical or health physics may be substituted on a year for year basis; or

2.6.6.9.3 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

2.6.6.10 For the purpose of RHB 2.6, the required work experience may be gained while working for a manufacturer or while working under the direct supervision of a vendor registered in the particular class.

2.6.6.11 Any person not meeting the requirements of this Part may apply to the Department for vendor registration, provided such person demonstrates education, training, and experience which is equivalent to that required for a particular class.

2.6.6.12 Any person registered prior to the effective date of this regulation as a vendor shall meet the education, training, and experience requirements of this Part no later than 24 months after the effective date of these regulations.

2.6.6.13 The Department shall initiate action to terminate the registration of any person who fails to comply with RHB 2.6.6.12.

2.6.7 Any branch office of a vendor shall be considered a separate entity and shall be registered separately pursuant to RHB 2.6.

2.6.8 Approval not Implied. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Department or that any activity under such registration has been approved by the Department.

RHB 2.7 Vendor Obligation.

2.7.1 Any person who sells, leases, transfers, lends, moves, assembles or installs x-ray machines in this State shall notify the Department within thirty days of:

2.7.1.1 The name and address of persons who have received these machines;

2.7.1.2 The manufacturer, the control and tube(s) model number, the control and tube(s) serial number of each radiation machine transferred; and

2.7.1.3 The date of transfer of each x-ray machine.

2.7.1.4 Notification to the Department shall be made on DHEC Form 823. A DHEC 823 form shall be submitted to the Department each month by Class I and Class II vendors regardless of whether x-ray equipment was sold that month. A vendor may be exempted from monthly reporting upon written request by the Department.

2.7.2 No person shall make, sell, lease, transfer, lend, maintain, repair, assemble, reassemble, reinstall or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used meet the requirements of these regulations. Each vendor shall ensure that the facility it is providing with services or supplies is registered with the Department prior to providing services or supplies.

2.7.3 Each vendor shall maintain records for review by the Department. These records shall include, at a minimum:

2.7.3.1 All information required by RHB2.7.

2.7.3.2 A copy of the shielding plan, if one was required, and if provided by that vendor;

2.7.3.3 Tests performed at the time of installation to ensure that the equipment complies with these regulations. A copy of these results shall be provided to the registrant at the time of installation;

2.7.3.4 Records of any routine maintenance, repair, alterations, or reassembly of x-ray equipment. Records of maintenance, repair, alterations, or reassemblies shall include the date that the service was performed. A copy of these records shall be provided to the registrant at the time the service is provided;

2.7.3.5 Names of all employees and their dates of employment with the vendor. Records shall also be maintained of training provided to the employees during their term of employment.

2.7.3.6 Records of equipment performance testing, including data collected during the testing. A copy of the equipment performance test must be provided to the facility either at the time of testing, or within thirty days of the testing date. The report of equipment performance testing shall include the testing of all items listed in Part IV, Appendix F, except as noted in the Appendix. The equipment performance test record provided to the facility must clearly indicate all equipment parameters tested, and must include a designation, such as "Pass/Fail" or "Compliant/Non-compliant", that is easily understandable by the facility. Use of any designation other than "Pass/Fail" or "Compliant/Non-compliant" shall be approved by the Department prior to use on equipment performance reports of testing. If the equipment performance test record includes any recommendations for improvement, such recommendations shall be clearly indicated as a recommendation. The record of equipment performance shall include the date that the testing was performed.

2.7.4 All records required by this Part shall be maintained by the vendor until their disposal is authorized by the Department. All records shall be accurate and factual.

2.7.5 Each vendor shall maintain sufficient calibrated and operable instruments to perform the testing appropriate to the class in which the vendor is registered. Instruments must be calibrated with sources consistent with the conditions under which they are used. Records shall be maintained of the calibrations performed on instrumentation used for testing. Instruments used shall be calibrated at the following frequencies:

2.7.5.1 Ion chambers and survey meters used for equipment performance testing and radiation area surveys shall be calibrated at intervals not to exceed twelve months and after each instrument servicing.

2.7.5.2 Ion chambers used for calibration of therapy units to meet the requirements of Part VI shall be calibrated at intervals not to exceed twenty four months and after each instrument servicing.

2.7.5.3 Other instruments used in performance testing of equipment, such as light meters, mAs meters, and kVp meters, shall be calibrated at intervals not to exceed twenty four months and after each instrument servicing.

RHB 2.8 Out of State X-ray Machines.

2.8.1 Whenever an x-ray machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Department at least two working days before such machine is to be used in the State. The notice shall include:

2.8.1.1 The type of x-ray machine.

2.8.1.2 The exact location where the machine is to be used;

2.8.1.3 The date(s) the machine is to be used; and

2.8.1.4. The state the machine is registered in and the registration number. If the machine is not registered in another state, the machine shall be registered with the Department.

2.8.2 If for a specific case the two working day period would impose an undue hardship on the person, he may, upon application to the Department, obtain permission to proceed sooner.

2.8.3 In addition the out-of-state registrant shall:

2.8.3.1 Comply with all applicable regulations of the Department;

2.8.3.2 Supply the Department with such other information as the Department may request; and

2.8.3.3 Not operate within the state on a temporary basis in excess of 180 calendar days per year.

RHB 2.9 Modification, Revocation, Termination of Registrants.

2.9.1 The terms and conditions of all registrations are subject to amendment, revision, or modification and all registrations are subject to suspension or revocation by reason of:

2.9.1.1 Amendments to the Act;

2.9.1.2 Rules and regulations adopted pursuant to provisions of the Act; or

2.9.1.3 Orders issued by the Department.

2.9.2 Any registration may be revoked, suspended, or modified in whole or part:

2.9.2.1 For any material false statement in the application or in any statement of fact required by provisions of this part;

2.9.2.2 Because of any statement of fact, any report, record, inspection, or other means which would warrant the Department to refuse to grant a registration on original application; or

2.9.2.3 For violations of, or failure to observe any of the terms and conditions of the Act, the registration, these regulations, or any order of the Department.

2.9.3 An order of revocation may be appealed as a contested case pursuant to Regulation 61-72. Emergency orders requiring immediate cessation of operations may be appealed for an expedited hearing which shall be provided within 72 hours of the request.

2.9.4 Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the Department shall:

2.9.4.1 Call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

2.9.4.2 Provide an opportunity for the registrant to demonstrate or achieve compliance with all regulations.

2.9.5 The Department may terminate a registration upon written request submitted by the registrant to the Department.

2.9.6 The provisions of this part shall apply to both registration of x-ray equipment and registration of x-ray services (vendors).

RHB 2.10 Annual Fees.

2.10.1 Any person issued or granted a registration for the possession and use of x-ray machine(s) shall pay an annual registration fee per machine tube. Vendors shall pay an annual flat fee. The annual registration fee shall be due on January 15 of each year.

2.10.2 Persons failing to pay the fees required by RHB 2.10.1 by March 15 of that year shall also pay a penalty of Fifty Dollars. If the required fees are not paid by April 15 of that year, the registrant shall be notified by certified mail to be sent to his last known address that his registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

2.10.3 A registrant suspended for failure to pay the required fee under RHB 2.10.2 may be reinstated by the Department upon payment of the required fee, the penalty of Fifty Dollars and an additional penalty of One Hundred Dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fee.

2.10.4 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

2.10.5 Fees required by RHB 2.10.1 for an x-ray machine or vendor registration which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

2.10.6 Schedule of Fees. The following fee schedule shall be used by the Department to determine the annual fee due:

Type of Equipment	Fee
Radiographic	$100
Fluoroscopic	100
Combination Rad/Fluoro	200
Dental	62.50
Therapy	125

Diffraction	68.75
X-ray Fluorescence	68.75
Accelerator	125
Electron Microscope	37.50
Spectrograph	68.75
Cephalometer	100
Panoramic	50
Cabinet X-ray	93.75
CT Scanner	100
C-Arm Fluoroscopic	100
Mammography	(See RHB 5.6)
Stereotactic Mammography	100
Baggage Checker	68.75
Bone Densitometer	100
Lithotripter	100
Type of Equipment	Fee
Simulator	100
Other	100
Vendors and Installers	156.25